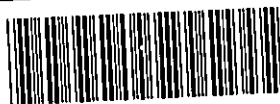


Media Release

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ROCHE HOLDING 82-3315

Roche



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Basel, 22 October 2007

Tarceva approved for lung cancer in Japan

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Roche, Chugai and OSI Pharmaceuticals, Inc. announced today that Tarceva (erlotinib) has been approved in Japan for the treatment of patients with nonresectable, recurrent and advanced non-small cell lung cancer (NSCLC) which is aggravated following chemotherapy. The Japanese Ministry of Health approval means that lung cancer patients in Japan will now have an important new treatment option which has been demonstrated to increase overall survival and offer an improvement in quality of life.

Over one million people worldwide suffer from NSCLC. It is the most common form of lung cancer and is more deadly than colon, breast, and prostate cancers combined.¹ In 2005, the number of newly diagnosed patients with NSCLC in Japan reached 85,000.²

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"Tarceva has proven to prolong survival and improve the quality of life of patients with the most common and deadly form of lung cancer," says William M. Burns, CEO of the Pharmaceuticals Division at Roche. "This approval in Japan underscores our commitment to ensure that eligible patients around the world will have access to this effective treatment."

"This is a huge milestone for lung cancer patients in Japan," said Gabriel Leung, President OSI Oncology. "The Japanese authorities have recognized the proven benefits of Tarceva and have acted admirably to make a significant difference to local patients, caregivers and oncologists battling this devastating disease."

Leung
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Tarceva's approval in Japan is based on the submission of two Phase II studies that confirmed the safety and efficacy of Tarceva in Japanese patients, along with data from the landmark, randomised, Phase III BR.21 study which compared Tarceva to placebo in patients with advanced NSCLC after failure of at least one prior chemotherapy regimen. In this study, 31% of patients

receiving Tarceva were alive at one year compared to 22% in the placebo arm and patients experienced a 42.5% improvement (6.7 months vs. 4.7 months) in the length of overall survival.³ In addition, significantly more patients on Tarceva had improvement in cough, pain, shortness of breath and overall physical function versus patients on placebo.³ The BR.21 study, also published in the *New England Journal of Medicine*, has led to the approval of Tarceva in over 80 countries including the United States and the European Union for the treatment of patients with locally advanced or metastatic NSCLC after failure of at least one prior chemotherapy regimen.

Chugai Pharmaceutical, Co., Ltd., a member of the Roche group, submitted the filing for this approval on April 14, 2006 to the Japanese Ministry of Health, Labour and Welfare. Following this formal approval, Tarceva is expected to launch in Japan by early 2008.

About Lung Cancer

According to the World Health Organisation, lung cancer is the most common cancer worldwide, with 1.2 million new cases annually.⁴ NSCLC accounts for almost 80 percent of all lung cancer cases.⁵ In Japan specifically, the estimated incidence of lung cancer was 85,000 cases in 2005.²

Additional Tarceva Information

Tarceva is a small molecule designed to target the human epidermal growth factor receptor 1 (HER1) pathway, one of the factors critical to cell growth in NSCLC and other solid tumors. HER1, also known as EGFR, is a component of the HER signalling pathway, which plays a role in the formation and growth of numerous cancers. Tarceva is designed to inhibit the tyrosine kinase activity of the HER1 signalling pathway inside the cell, which may block tumor cell growth. Tarceva is the only HER1/EGFR-targeted therapy proven to significantly prolong survival in second-line NSCLC as a single agent.

Tarceva was approved by the FDA in November 2004 and in the European Union in September 2005 as monotherapy for the treatment of patients with locally advanced or metastatic non-small cell lung cancer (NSCLC) after failure of at least one chemotherapy regimen.

In November 2005, the U.S. Food and Drug Administration (FDA) approved the use of Tarceva in combination with gemcitabine for the first-line treatment of patients with locally advanced, unresectable or metastatic pancreatic cancer in patients who have not received previous chemotherapy. In January 2007, the European Commission granted marketing authorization for Tarceva in combination with gemcitabine for the treatment of metastatic pancreatic cancer. Tarceva is the first drug in a Phase III trial to have shown a significant improvement in overall survival when added to gemcitabine chemotherapy as an initial treatment for pancreatic cancer.

For more information, please visit <http://www.tarceva.com>.

About OSI

OSI Pharmaceuticals is committed to "shaping medicine and changing lives" by discovering, developing and commercializing high-quality and novel pharmaceutical products designed to extend life and/or improve the quality of life for patients with cancer and diabetes/obesity. The Company's oncology programs are focused on developing molecular targeted therapies designed to change the paradigm of cancer care. OSI's diabetes/obesity efforts are committed to the generation of novel, targeted therapies for the treatment of type 2 diabetes and obesity. OSI's flagship product, Tarceva (erlotinib), is the first drug discovered and developed by OSI to obtain FDA approval and the only EGFR inhibitor to have demonstrated the ability to improve survival in both non-small cell lung cancer and pancreatic cancer patients in certain settings. OSI markets Tarceva through partnerships with Genentech, Inc. in the United States and with Roche throughout the rest of the world. For additional information about OSI, please visit <http://www.osip.com>.

About Chugai

Chugai Pharmaceutical, specializes in prescription pharmaceuticals and based in Tokyo, is Japan's leading research-based pharmaceutical companies with strengths in biotechnology products. Since the start of the strategic alliance with Roche in October 2002, Chugai is actively involved in prescription pharmaceutical R&D activities in Japan and abroad as an important member of the Roche Group. Specifically, Chugai is working to develop innovative products with global applications, focusing on the disease areas of oncology, renal disease, and bone and joint. In Japan, Chugai's research facilities in Gotemba and Kamakura are collaborating to develop new pharmaceuticals and Ukima is conducting research for technology development for industrial production. Overseas, Chugai Pharma USA and Chugai Pharma Europe are engaged in clinical development activities in the United States and Europe. Additional information is available on the Internet at www.chugai-pharm.co.jp/hc/chugai_top_en.jsp

About Roche

Headquartered in Basel, Switzerland, Roche is one of the world's leading research-focused healthcare groups in the fields of pharmaceuticals and diagnostics. As the world's biggest biotech company and an innovator of products and services for the early detection, prevention, diagnosis and treatment of diseases, the Group contributes on a broad range of fronts to improving people's

health and quality of life. Roche is the world leader in in-vitro diagnostics and drugs for cancer and transplantation, a market leader in virology and active in other major therapeutic areas such as autoimmune diseases, inflammation, metabolic disorders and diseases of the central nervous system. In 2006 sales by the Pharmaceuticals Division totalled 33.3 billion Swiss francs, and the Diagnostics Division posted sales of 8.7 billion Swiss francs. Roche has R&D agreements and strategic alliances with numerous partners, including majority ownership interests in Genentech and Chugai, and invests approximately 7 billion Swiss francs a year in R&D. Worldwide, the Group employs about 75,000 people. Additional information is available on the Internet at www.roche.com.

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Roche Group Media Office

Phone: +41 61 688 88 88 / Email: basel.mediaoffice@roche.com

- Daniel Piller (Head Roche Group Media Office)
- Baschi Dürr
- Martina Rupp
- Claudia Schmitt

References:

1. http://www.umm.edu/patiented/articles/what_lung_cancer_000072_1.htm.
2. A. Oshima, T. Kuroishi, K. Tajima, "Cancer White Paper -Incidence/Death/Prognosis – 2004."
3. Shepherd FA, Pereira JR, Ciuleanu T, Tan EH, *et al*. Erlotinib in previously treated non-small-cell lung cancer. *New England Journal of Medicine* 2005; 353:123.
4. IARC. GLOBOCAN 2002. Cancer Incidence, Mortality and Prevalence Worldwide (2002 estimates). Accessed 2007 (<http://www-dep.iarc.fr/>).
5. Wilking N and Jonsson B. (2005) A Pan-European comparison regarding patient access to cancer drugs, Karolinska Institute in collaboration with Stockholm School of Economics, Stockholm, Sweden.



Basel, 23 October 2007

Roche Considering Legal Options In Patent Litigation Case

Roche announced today that a jury in the U.S. District Court in Massachusetts found in favour of Amgen in the patent infringement dispute relating to the Roche erythropoiesis-stimulating agent, MIRCERA. Roche is currently evaluating its legal options, including the possibility of an appeal.

Roche maintains its position that all of Amgen's patents for epoetin asserted against Roche are invalid and not infringed, and believes the facts and the law support that position.

"The verdict is disappointing because in the end, it is U.S. patients with chronic kidney disease who lose. Amgen has had an extended monopoly for the last 20 years in the U.S. blocking new therapeutic options to treat anaemia from being introduced," said William M. Burns, CEO of the Pharma Division at Roche.

MIRCERA is currently awaiting FDA approval which is expected on November 14th. MIRCERA was already approved in July in the European Union and in Switzerland and Norway in September. MIRCERA has been recently launched in Austria, Sweden, Germany and the UK. Studies with MIRCERA have shown that the treatment corrected and maintained haemoglobin levels as well as existing ESAs but with fewer injections than currently available erythropoiesis-stimulating agents (ESAs).ⁱ One of the pivotal studies from its Phase III program was just published in *The Lancet*.ⁱⁱ

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and treatment of diseases, the Group contributes on a broad range of fronts to improving people's health and quality of life. Roche is the world leader in in-vitro diagnostics and drugs for cancer and transplantation, a market leader in virology and active in other major therapeutic areas such as autoimmune diseases, inflammation, metabolism and central nervous system. In 2006 sales by the Pharmaceuticals Division totalled 33.3 billion Swiss francs, and the Diagnostics Division posted sales of 8.7 billion Swiss francs. Roche employs roughly 75,000 worldwide and has R&D agreements and strategic alliances with numerous partners, including majority ownership interests in Genentech and Chugai. Additional information about the Roche Group is available on the Internet at www.roche.com.

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ⁱ In the EU, for patients not currently treated with an erythropoiesis stimulating agent (ESA), the recommended starting dose is 0.6 microgram/kg body weight, administered once every two weeks as a single intravenous or subcutaneous injection in order to increase the haemoglobin to greater than 11 g/dl (6.83 mmol/l). Patients currently treated with an ESA can be converted to MIRCERA administered once a month as a single intravenous or subcutaneous injection. The starting dose of methoxy polyethylene glycol-epoetin beta is based on the calculated previous weekly dose of darbepoetin alfa or epoetin at the time of substitution. Summary of Product Characteristics for MIRCERA in the EU, www.emea.europa.eu. Darbepoetin alfa in the correction phase, the initial dose by subcutaneous or intravenous administration is 0.45 µg/kg body weight, as a single injection once weekly. Alternatively, in patients not on dialysis, an initial dose of 0.75 µg/kg may be administered subcutaneously as a single injection once every two weeks. In the maintenance phase, Aranesp may continue to be administered as a single injection once weekly or once every two weeks. In patients not on dialysis, once the target haemoglobin has been achieved with once every two week dosing, Aranesp may be administered subcutaneously once monthly using an initial dose equal to twice the previous once every two week dose. In the US, darbepoetin alfa The recommended starting dose of Aranesp® for the correction of anemia in adult CRF patients is 0.45 mcg/kg body weight, administered as a single IV or SC injection once weekly. Because of individual variability, doses should be titrated to achieve and maintain the lowest hemoglobin level sufficient to avoid the need for RBC transfusion and not to exceed 12 g/dL.

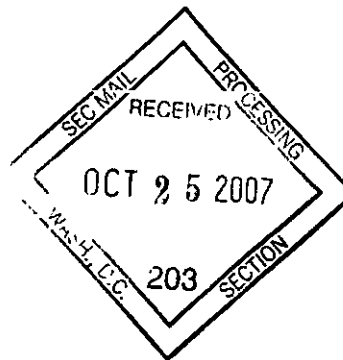
The use of Aranesp® in pediatric CRF patients as the initial treatment to correct anemia has not been studied. In the maintenance phase Aranesp® dosage should be adjusted to maintain the lowest hemoglobin level sufficient to avoid the need for RBC transfusion and not to exceed 12 g/dL. Doses must be individualized to ensure that hemoglobin is maintained at an appropriate level for each patient (see Dose Adjustment). For many patients, the appropriate maintenance dose will be lower than the starting dose. Predialysis patients, in particular, may require lower maintenance doses. Some patients have been treated successfully with a SC dose of Aranesp® administered once every 2 weeks.

ⁱⁱ Levin NW. Intravenous methoxy polyethylene glycol-epoetin beta for haemoglobin control in patients with chronic kidney disease who are on dialysis: a randomized non-inferiority trial (MAXIMA). The Lancet; 370: 1415-1421.

Investor Update

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Roche



Basel, 24 October 2007

Roche announces positive results in solid tumors using human monoclonal antibody against IGF-1R (R1507)

Today, Roche announced positive results from a Phase I trial of R1507, a human monoclonal antibody to target IGF-1R (insulin-like growth factor receptor), in patients with solid tumors. IGF-1 is one of the most potent natural activators of the AKT and MAPK signaling pathways, which promote cell growth and cell survival. The IGF-1R pathway has also been shown to have an important role in mediating the resistance to cytotoxic drugs and EGFR/HER2-targeted agents. The results were reported during the AACR-NCI-EORTC International Conference on Molecular Targets and Cancer Therapeutics, held in San Francisco.

Study Results

In the Phase I study, R1507 was administered by intravenous infusion. Nine of 34 adult patients with advanced solid tumors experienced disease stabilization. Four of the seven heavily pretreated patients with Ewing's sarcoma demonstrated clinical benefit with two of these patients achieving durable, objective partial responses.

Once a week administration of R1507 was well tolerated with very few side effects. Treatment with R1507 was not associated with the typical side-effects normally observed with cancer therapy (e.g., low blood counts, infection, hair loss, severe nausea and vomiting). The most frequent side effects observed were fatigue, anorexia and weight loss, symptoms that are commonly observed in patients with advanced cancer.

"We are very encouraged by these early results with R1507 in patients with refractory Ewing's sarcoma," said Kapil Dhingra, MD, Head, Oncology Disease Biology Area at Roche. "As a result, we have given this program a very high priority as we believe this molecule has the potential to be very beneficial in treating patients with sarcoma as well as a variety of other solid tumors."

The antibody (R1507) was initially developed under Roche's broad antibody development collaboration with Genmab, which began in 2001.

The Phase I study is being conducted at four sites in the U.S., including the University of Colorado Cancer Center (Auroro, CO), The University of Texas M.D. Anderson Cancer Center (Houston, TX), Cancer Institute of New Jersey (New Brunswick, NJ) and The Institute for Drug Development (San Antonio, TX). R1507 has also been investigated in 26 patients on a three week schedule in the Phase I study. This treatment schedule was also generally well tolerated with a side effect profile similar to the weekly schedule.

"This drug attacks the IGF pathway and may provide a new class of drugs to treat a variety of cancers, including breast, prostate, colon, melanoma, myeloma and a variety of sarcomas, which could greatly add to the way that we currently treat these patients," says Stephen Leong, M.D., assistant professor of Medical Oncology at the University of Colorado Cancer Center and lead author of the abstract.

Razelle Kurzrock, MD, investigator at the M.D. Anderson Cancer Center and the senior author of the abstract, noted that some of the responses were very impressive. For instance, one 28 year-old Ewing's sarcoma patient with large tumors unresponsive to many other treatments showed dramatic tumor shrinkage within six weeks, without side effects. "This is one of the best responses I've seen in over 20 years of oncology experience," stated Dr Kurzrock.

Based on these initial results with R1507, Roche plans to conduct additional trials and work with a global consortium of sarcoma experts, including the Sarcoma Alliance for Research through Collaboration (SARC). "We are very excited about our collaboration with SARC, which represents a new approach to sarcoma clinical trials, and we look forward to combining our expertise with that our colleagues at SARC to expedite new sarcoma treatments," added Dhingra.

"We are excited to be partnering with Roche on the development of a new treatment against an important target, which could result in a potential breakthrough treatment for sarcoma as well as other cancers," said Laurence Baker, DO, Professor of Medicine and Pharmacology at the University of Michigan and the Executive Director, SARC. "With Roche's considerable expertise in oncology and SARC's vast network of physicians and institutions, we look forward to determining the potential of R1507 in this important disease area."

About Ewing's Sarcoma

The Ewing's family of tumors (EFT) includes primary tumors of bone (classic Ewing's sarcoma, primitive neuroectodermal tumor, and Askin tumor) and extraosseous primary tumors (National Cancer Institute). Studies using immunohistochemical markers, cytogenetics, molecular genetics,

and tissue culture indicate that these tumors are all derived from the same primordial stem cell. EFTs account for 4 percent of childhood and adolescent malignancies. The estimated incidence (US) is approximately 300 new cases per year. The median age for patients with EFT is 15 years and more than 50 percent of patients are adolescents. There is a slight male predominance and the lower limbs are affected in 40 percent of the patients.

Approximately 20 to 30 percent of the patients with ETB have overt metastases at the time of diagnosis. However, outcomes for patients with metastatic disease have improved little during the last 20 years. Approximately 25-30 percent survival could be achieved with current therapies for patients who present with metastatic disease at initial diagnosis.

About SARC

The purpose of the Sarcoma Alliance for Research through Collaboration (SARC) is to engage all appropriate and necessary resources to cure and prevent sarcoma. SARC brings together expert sarcoma researchers and clinicians from 29 centers of excellence in the United States. SARC by the charter, promotes international collaboration in sarcoma clinical trials through its association with European sarcoma experts. SARC is unique as a clinical trial organization in that its trials at the inception include pediatric and medical patients with sarcoma, because sarcomas affect people of all ages. SARC is a 501c3, non-profit organization that is headquartered in Ann Arbor, Michigan.

About Roche

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Roche IR Contacts:

Dr. Karl Mahler
Phone: +41 (0)61 687 85 03
e-mail: karl.mahler@roche.com

Dianne Young
Phone: +41 (0)61 688 93 56
e-mail: dianne.young@roche.com

Carla Bedard
Phone: +41 (0)61 687 13 00
e-mail: carla_christine.bedard@roche.com

Dr. Nicolas Dunant
Phone: +41 (0)61 687 05 17
e-mail: nicolas.dunant@roche.com

North American investors please contact:

Thomas Kudsk Larsen
Phone: +1 973 235 36 55
Mobile phone: +1 973 393 53 15
e-mail: thomas_kudsk.larsen@roche.com

General inquiries:

International: +41 (0)61 688 88 80
North America: +1 973 562 22 33
e-mail: investor.relations@roche.com

END